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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,025	03/02/2004	Robert Frederick Veasey	02481.1836	9747
22852 7590 04/30/2009 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				
			EXAMINER PATEL, SHEFALI DILIP	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 04/30/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/790,025

**Applicant(s)**

VEASEY ET AL.

**Examiner**

SHEFALI D. PATEL

**Art Unit**

3767

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02/17/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9,10 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,11-15,17,18 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB008)
- Paper No(s)/Mail Date 02/17/2009.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Acknowledgments***

1. In the reply, filed on February 17, 2009, Applicant amended claims 1, 2, and 8.
2. Applicant cancelled claims 19-21.
3. Applicant added new claim 22.
4. In the non-final rejection of October 14, 2008, Examiner objected to the Abstract for use of the term "means" with respect to several elements. Applicant corrected some of the elements; however, "ratchet means" and "clutch means" remain. Therefore, the objection is maintained.
5. Examiner objected to the Specification for not containing section headings. Applicant amended the Specification to include section headings. Objection is withdrawn.
6. Examiner objected to claims 2 and 7 for minor informalities. Applicant amended claim 2 but did not amend claim 7. Examiner considered and agreed with the remarks of the Applicant in reference to claim 7 (Reply, page 11). Objection is withdrawn.
7. Examiner rejected claim 8 under 35 USC 112, 2nd paragraph for insufficient antecedent basis for the term "the cylindrical portion". Applicant amended claim 8. Rejection is withdrawn.
8. Examiner did not examine claim 9, as it appeared to be drawn to a non-elected Species II (Figure 6) (Specification, page 13, lines 5-10). Applicant remarks that "the rigid keying" feature of claim 9 is applicable to elected Species I (Figures 1-5); however, there is no specific recitation of the limitation "rigid keying" in the Specification in relation to Figures 1-5. Therefore, the withdrawal of claim 9 is maintained.
9. Currently, claims 1-4, 7, 8, 11-15, 17, 18, and 22 are under examination.

***Response to Arguments***

10. Applicant's arguments filed on February 17, 2009, have been fully considered but they are not persuasive:

In regards to the 35 USC 102(b) rejection of claim 1 under Moller, Applicant argues that the cartridge of Moller is not contained within the housing (Reply, page 12). However, Moller states that "an elongated cylindrical housing 1 has a partitioning wall 2 which divides the housing in a compartment containing a dose setting mechanism and **a compartment 3 designed for the accommodation of a not shown ampoule.**" (paragraph [0022]). Since the compartment [3] is a section of the housing [1], at least a portion of the cartridge ("ampoule") will be contained within the housing when the cartridge is inserted into the compartment [3] (Figure 1).

In regards to the 35 USC 102(b) rejection of claim 2 under Moller, Applicant argues that Moller fails to teach ratchet means associated with the insert to ensure the piston rod only rotates in a single direction through the insert. Applicant further argues that the ratchet means [13] can move up and down along the thread of the piston rod [4] and thus allows the bidirectional rotation of the piston rod [4] relative to the ratchet means [13] (pages 13-14). However, Moller never states bidirectional rotation of the piston rod. Moller states that the ratchet means [13] screws up along the thread of the piston rod [4] (paragraph [0030]); therefore, the piston rod is naturally capable of rotating in the opposite direction of rotation of the ratchet means. Moller further states that the ratchet means [13] and the piston rod [4] move down together without rotation to inject a dose (paragraph [0032]). Therefore, Moller never indicates that the piston rod

is capable of rotating in two directions. The piston rod of Moller is only capable of rotating in one direction (paragraph [0030]).

### *Specification*

11. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

**The new abstract contains the terms "ratchet means" and "clutch means".**

### *Claim Rejections - 35 USC § 102*

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4, 7, 8, 11-15, 17, 18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Moller (US 2002/0052578).

In regards to claim 1, Moller teaches a pen-type injector (Figures 1-2) comprising:

- a. a housing (housing [1])

- b. a cartridge (ampoule, not shown) containing medicinal product, the cartridge being retained within the housing [1] (paragraph [0022])
- c. a dose selecting means for selecting a dose of medicinal product to be expelled (dose setting drum [17])
- d. a dose expelling means for expelling the selected dose of medicinal product (tubular part [20])
- e. wherein the housing [1] comprises a unitary housing within which the dose selecting means [17] and the dose expelling means [20] are moveably retained (paragraphs [0022][0025][0026])

In regards to claim 2, Moller teaches a pen-type injector (Figures 1-2) comprising:

- a. a housing (housing [1])
- b. a piston rod (threaded piston rod [4]) having a screw thread
- c. an insert (partitioning wall [2], tubular element [5], connection bars [12]) located in the housing [1] and through which the piston rod [4] may rotate (Figure 1)
- d. ratchet means (nut [13]) associated with the insert to ensure the piston rod [4] only rotates in a single direction through the insert (paragraph [0024])
- e. a dose dial sleeve (dose setting drum [17]) rotatable with respect to the housing [1] and the insert
- f. a drive sleeve (tubular part [20]) which is axially displaceable but not rotatable with respect to the piston rod [4]

- g. a button (button [18]) located on the drive sleeve [20] and rotatable with respect to the drive sleeve (paragraph [0029])
- h. clutch means (coupling [21]) which upon depression of the button [18] prevents rotation between the dose dial sleeve [17] and the drive sleeve [20] (paragraph [0029])

In regards to claim 3, Moller teaches that the injector further comprises a nut (ring [25]) which is rotatable with respect to the drive sleeve [20] and axially displaceable but not rotatable with respect to the dose dial sleeve [17] (paragraph [0027]).

In regards to claim 4, Moller teaches that the insert comprises a web [2] having an opening (central opening, not referenced), the web [2] being a first cylindrical portion, a second cylindrical portion [5] extending from a second side of the web, and a third cylindrical portion [12] extending from a second side of the web.

In regards to claims 7 and 8, Moller teaches that the dose dial sleeve [17] comprises a first section of first diameter, the first section including interengaging features to provide a helical thread (internal thread, not shown, and outer thread [7]) between the insert and the dose dial sleeve (paragraph [0025]).

In regards to claim 11, Moller teaches that an outer surface of the dose dial sleeve [17] includes graphics (numbers on a helical scale, not shown) and wherein the housing [1] is provided with a window (window, not shown) through which a portion of the graphics may be viewed (paragraph [0025]).

In regards to claim 12, Moller teaches that the drive sleeve [20] comprises a first part of first diameter located between the insert [2] and the piston rod [4] and a second part of second diameter located between the piston rod [4] and the dose dial sleeve [17], an internal surface of the drive sleeve [20] being splined to the piston rod [4] such that relative rotation between the drive sleeve and the piston rod is prevented while longitudinal displacement is permitted (Figure 1) (paragraph [0033]).

In regards to claims 13 and 15, Moller teaches that the drive sleeve [20] further comprises a central receiving area having a peripheral recess (Figure 1), and wherein the button [18] being of generally "T" shaped configuration has a stem that is retained within the receiving area by co-operation between a peripheral bead [33] provided on the stem retained in a peripheral recess [32] provided in the central receiving area (Figure 1) (paragraphs [0029][0033]).

In regards to claim 14, Moller teaches that the nut [25] is provided on a helical thread provided on the drive sleeve [20] and is located between the drive sleeve [20] and the dose dial sleeve [17], the dose dial sleeve and the nut being splined together by spline means (spring [26]) to prevent relative rotation between the nut and the dose dial sleeve (paragraph [0027]).

In regards to claim 17, Moller teaches that the clutch means [21] comprises a plurality of radially extending longitudinally directed teeth (protrusions [32][33]) provided respectively on the dose dial sleeve [17] and the drive sleeve [20] (paragraph [0029]).

In regards to claim 18, Moller teaches that clicker means are provided between the dose dial sleeve [17] and the drive sleeve [20], the clicker means comprising a plurality of longitudinally extending teeth (rosette of V-shaped teeth of drive sleeve [20], not referenced) and



a flexible toothed member (teeth [24]), wherein relative rotation between the dose dial sleeve and the drive sleeve causes the flexible toothed member to ride over the teeth to produce a series of clicks (paragraphs [0027][0029]).

In regards to claim 22, Moller teaches a pen-type injector (Figures 1-2) comprising:

- a. a housing (housing [1])
- b. a cartridge (ampoule, not shown) containing medicinal product, the cartridge being retained within the housing [1] (paragraph [0022])
- c. a piston rod (piston rod [4])
- d. a dose selecting means for selecting a dose of medicinal product to be expelled (dose setting drum [17])
- e. a dose expelling means for expelling the selected dose of medicinal product (tubular part [20], nut [13])
- f. wherein the dose expelling means [20][13] directly engages an end of the piston rod [4], and the housing [1] comprises a unitary housing within which the dose selecting means [17] and the dose expelling means [20] are moveably retained (paragraphs [0025][0026][0030][0032])

### *Conclusion*

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/  
Examiner, Art Unit 3767  
04/28/2009  
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